

### **REMARKS**

Applicants thank Examiner Yao for the telephonic interview with the undersigned attorney on July 24, 2007, and particularly for her helpful suggestions on claim amendment.

#### **I. Status of the Claims**

Claims 7-14, 18, 19, 21, 22, and 24-33 are pending in this application, with claims 8, 10, 12-14, 19, 21, 22, and 24-28 withdrawn from consideration for the time being. The Examiner has indicated the allowability of claim 18.

Upon entry of the present amendment, claim 7 is amended to recite that the claimed CD-30 binding reagent is (1) an antibody produced by the cell DSZ1 stored at the German Microorganisms Collection (DSM) under the number DSM ACC2548; (2) a humanized version of the antibody of (1); or (3) a binding fragment of either the antibody of (1) or the humanized antibody of (2). This amendment merely rewrites the claim to improve clarity. Claim 9 is amended to change its base claim from claim 8 to claim 7. Because this amendment introduces no new matter and requires no new searches, its entry is respectfully requested.

#### **II. Claim Objections**

In the Final Office Action of June 13, 2007, the Examiner has again objected to claim 9 for alleged improper dependency from claim 8. Claim 9 has now been amended to depend from claim 7. The objection is thus overcome.

#### **III. Sequence Requirements**

The Examiner has also objected to the specification for failure to comply with the sequence requirements, in particular, on page 16 of the substitute specification where several primer sequences are provided without their respective sequence identifiers. The objection is overcome in view of the present amendment to the specification.

#### IV. Claim Rejections

##### A. 35 U.S.C. §102

Claims 7, 29, and 30 are rejected under 35 U.S.C. §102(b), for alleged anticipation by Lemke *et al.* (U.S. Patent No. 6,033,876). Specifically, the Examiner argues that, since the Lemke reference describes a CD30 antibody, Ber-H2, and its humanization, the pending claims would be anticipated by Lemke's teaching, particularly the part directed to the humanized antibody (see, *e.g.*, page 4 of the Final Office Action). Applicants respectfully traverse the rejection.

To anticipate a pending claim, a prior art reference must provide, either explicitly or inherently, each and every limitation of the pending claim. MPEP §2131. As amended, the independent claim 7 is now directed to (1) an antibody produced by the cell DSZ1 stored at the German Microorganisms Collection (DSM) under the number DSM ACC2548; (2) a humanized version of the antibody of (1); or (3) a binding fragment of either the antibody of (1) or the humanized antibody of (2). As described in the specification, the antibody produced by the DSZ1 cells is a chimeric antibody that contains the human IgG1 $\kappa$  chain and the variable regions encoding the antigen-binding site for the CEPDY epitope of CD30. The variable regions come from rearranged genomic V<sub>H</sub>DJ and V<sub>L</sub>J segments, obtained by PCR using specially designed primers (see, *e.g.*, pages 12-13, in the paragraph immediately under the title "**1. Production of the antibody according to the invention**"). The genomic sequence of the variable domain leads to a reliable production of the antibody in a very large quantity (see, *e.g.*, on page 14, in the paragraph bridging pages 13 and 14). Thus, the claimed antibody or its fragment is narrowly defined based on the unique sequence features of the antibody produced by DSZ1 cells.

Applicants respectfully disagree with the Examiner's assertion that Lemke teaches the humanization of Ber-H2. The Examiner points to column 4, lines 52-60, and column 6 for the discussion of humanization. Yet the discussion relates to Lemke's new, inventive antibodies and does not relate to Ber-H2. Indeed, Ber-H2 is described by Lemke in column 2, lines 2-3, as an antibody that "labels a subpopulation of plasma cells." This is in direct contrast to the description of Lemke's "new antibodies according to this invention," which "do not bind to a

considerable extent to plasma cells" (column 2, lines 23-27). Therefore, Ber-H2 is clearly not one of Lemke's "inventive antibodies," only to which the humanization discussion pertains. Applicants thus take the view that Lemke provides no teaching of humanization of Ber-H2, let alone any teaching of humanization of the antibody produced by the DSZ1 cells.

Since the Lemke reference fails to provide each and every limitation of claim 7, it cannot anticipate the pending claims. Withdrawal of the rejection under 35 U.S.C. §102 over Lemke *et al.* is therefore respectfully requested.

B. 35 U.S.C. §103

Claims 9 and 11 remain rejected under 35 U.S.C. §103(a) for alleged obviousness over Lemke *et al.* in view of Deonarain *et al.* Applicants respectfully traverse the rejection, particularly in view of the present amendment.

In order to establish a *prima facie* showing of obviousness, three requirements must be satisfied: all limitations of a pending claim must be expressly or impliedly disclosed by prior art references; there must be a suggestion or motivation in the art for one skilled artisan to combine the limitations; and there must be a reasonable expectation of success in making such a combination. MPEP §2143. As discussed in the last section, the Lemke reference fails to provide every limitation of claim 7. On the other hand, the Deonarain reference is cited for the purpose of providing the limitations relevant only to dependent claims 9 and 11; it also fails to provide the missing limitations. As such, not all claim limitations can be found in the cited references. No *prima facie* obviousness can be established.

Accordingly, Applicants respectfully request that the Examiner withdraw the obviousness rejection under 35 U.S.C. §103.

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**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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